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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/541,037

06/28/2005

Klaus-Dieter Beller

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EXAMINER

SHOME, ARUNDIPTA

ART UNIT

PAPER NUMBER

4116

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/541,037	Applicant(s) BELLER, KLAUS-DIETER	
	Examiner ARUNDIPTA SHOME	Art Unit 4116	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6-28-2005</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's preliminary amendment filed on June 28, 2005 is acknowledged. Claims 1-7 are canceled and claims 8-13 are pending in this application. The amendment to the specification is also acknowledged.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 9 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claim 9, the limitation of "the cylinder wall" is indefinite because claim 8 recites a cylinder body and a unitary cylinder wall, both of which have cylinder walls.

For the purpose of examination, this limitation will be interpreted as relating to the unitary cylinder wall.

Regarding Claim 12, the limitation of "continuous relative to earth's horizontal" is unclear because the earth has no inherent horizontal plane that can be used for reference.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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2. Claims 8 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Whaley et al. (US Patent 6,119,688).

Regarding Claim 8, Whaley et al. discloses: a device for taking powdered, grainy, or granular substances (abstract). This device comprises a storage receptacle (11) for a substance (col. 6 line 37). Whaley also discloses a supply tube (16, Fig. 3) with a first end (18) for dispensing a substance.

Whaley also discloses that the supply tube (16) can be mounted for movement (col. 13, lines 27-35), in which case the second end of the tube would be pivotably supported.

Whaley also discloses a stationary cylinder body (22) (col. 13, lines 27-35).

Whaley also discloses that the second end of the supply tube comprises a unitary cylinder wall (30) pivotably mounted on the stationary cylinder body. Given that the supply tube can be made pivotable, the supply tube can be pivotable both when the device is in a position of non-use (Fig. 3) and a second position of use (Fig. 5). Whaley also discloses that the device can be used in two positions, a loading or non-use position and a delivery or use position (col. 13 lines 32-35).

In the first position of non-use (fig. 3) the substance is air-tightly closed off in the storage receptacle, and in the second position, the substance enters the supply tube (Fig. 5).

The cylinder body has a through bore (23).

The unitary cylinder wall has a through opening (32).

The supply tube has an inner opening as shown in Figure 3.

In the first position the inner opening of the supply tube (16) and the through opening (32) do not communicate with the through bore (23) of the cylinder body (Fig. 3).

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In the second position the inner opening of the supply tube (16) and the through opening (32) do communicate with the through bore (23) of the cylinder body (Fig. 5).

Regarding Claim 13, the device of Whaley is capable of the function recited in the claim. The Examiner notes that capsule could be inserted into through bore (23) through inlet end (18) (because the direction of insertion is not claimed) so that it extends past cylinder body (30). A force that then rotates cylinder (30) from the first position to the second position, as well as the pivotable supply tube, would be capable of shearing the opposed ends of the capsule off.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 9, 10, 12, are rejected under 35 U.S.C. 103(a) as being unpatentable over Whaley et al. (US Patent 6,119,688) in view of Goldemann et al. (US Patent 6,752,147).

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Regarding Claim 9, Whaley teaches that a predetermined dose of powder medicament (12) is transferred from the storage receptacle (11) into opening (32) (col. 8 lines 35-40). This shows that several dosage units of the medicament are contained in the storage receptacle (11).

Whaley does not disclose that the storage receptacle has a bottom side with an outlet opening. However, Goldemann et al. (US Patent 6,752,147) teaches a powder inhaler with a powder reservoir (12) and a powder discharge hole (12a). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add such an opening to the storage receptacle of Whaley so that powder is funneled above the area where the through opening (32) receives the powder.

The through opening (32) of the cylinder wall, in the first position of the supply tube, is located underneath where the outlet opening of Whaley/Goldemann would be (fig. 3), because Goldemann teaches that the powder discharge hole is located directly below the medication storage area (Fig. 1), as is obvious to one of ordinary skill in the art. In the second position, the through opening communicates with the through bore of the cylinder body (fig. 5).

Regarding Claim 10, the through bore (23) of the cylinder body extends radially (Fig. 5). Whaley et al. also discloses an upwardly extending continuous connecting bore (17). Whaley does not show in the figures that the connecting bore (17) is connected transversely to through bore (23), but discloses that through bore (23) can be made movable or rotatable. (col. 13, lines 27-35) Therefore if the through bore were rotated 90 degrees, it would be transverse to the connecting bore (17).

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The radially extending through bore (23) during inhalation defines a continuous airflow that entrains the substance present within the radially extending through bore, as shown in Figure 5.

The cylinder wall also has a remote opening shown in Figure 2 where pressurization assembly (20) is inserted. This opening is at the second end remote from the first end, and is provided on an axial extension of the supply tube.

The through opening of the cylinder wall, in the first position of the supply tube, is located underneath the outlet opening of the storage receptacle (see Fig. 3), and in the second position is positioned above the connecting bore of the cylinder body (Fig. 5).

Regarding Claim 12, the through bore (23) of the cylinder body is an angled through bore and has a slant that is continuous relative to the earth's horizontal (parallel, see Fig. 5). (Examiner also notes that the device could simply be rotated, and the through bore would then be slanted relative to the earth's horizontal). The through opening in the cylinder wall is arranged such that the through opening in the first position of the supply tube is located underneath the outlet opening (the addition of the outlet opening is noted with respect to claim 9) of the storage receptacle (see Fig. 3). The angled through bore (23) is closed by the cylinder wall in this position as well. The through opening in the second position is located above an inlet of the through bore of the cylinder bore (Fig. 5), and the inner opening (16) of the supply tube communicates with an outlet of the angled through bore (23, see Fig. 5).

6. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whaley et al. (US Patent 6,119,688) in view of Goldemann et al. (US Patent 6,752,147) further in view of Mecikalski (US Patent 6,055,980).

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Regarding Claim 11, Whaley et al. does not disclose a one way valve in the air channel defining the airflow. However, Mecikalski (US Patent 6,055,980) discloses a powder inhaler with a one way valve (123). It would have been obvious to one of ordinary skill in the art to add this valve to the device of Whaley et al. for preventing exhalation by the user into the apparatus so that no breath moisture is available to cake the powder, as is disclosed in Mecikalski (col. 7 line 30).

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
8. Herrold et al. (US Patent 5,505,196) discloses a powder inhaler with a rotating drum.
9. Braithwaite et al. (US Patent 6,845,772) discloses another powder inhaler with a rotating drum.
10. Braithwaite (US Patent 7,207,330 B1) discloses a powder inhaler with a rotating medicant metering member.
11. Schaeffer et al. (US Patent 6,065,471) discloses a powder inhaler with a pivotable exterior casing element.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ARUNDIPTA SHOME whose telephone number is 571-270-5539. The examiner can normally be reached on Monday-Friday from 8:30 am to 6:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Cheng, can be reached at 571-272-4433. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. Shome
Examiner, Art Unit 4116
8/13/2008

/Anu Ramana/

Primary Examiner, Art Unit 3733